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VB

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/024,988 02/17/98 NELSON

R 5015C1

HM12/0922

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EXAMINER

UNGAR, S

ART UNIT

PAPER NUMBER

1642

5

DATE MAILED:

09/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/024,988

Applicant(s)
Nelson et al

Examiner
Ungar

Group Art Unit
1642



☒ Responsive to communication(s) filed on Jul 2, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 31-47 is/are pending in the application.

Of the above, claim(s) 32, 34-39, and 42-47 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 31, 33, 40, and 41 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1642

1. The Election filed July 2, 1999 (Paper No. 4) in response to the Office Action of June 4, 1999 (Paper No. 3) is acknowledged and has been entered. Claims 31-47 are currently pending and Claims 32, 34-39 and 42-47 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions. Claims 31, 33 and 40-41 are currently under prosecution.

2. Applicant's election with traverse of species (b)(b), claims 31, 33 and 40-41 in Paper No 4 is acknowledged. The traversal is on the ground(s) that the Applicants right to embrace multiple species within the umbrella of an allowable generic claim should not be impaired by overly pedantic hyperbolization, particularly in view of the highly oppressive burden placed on small entities by the current maintenance fee requirements which are magnified if and when multiple patents are required for closely related, albeit technically distinctive, patent claims. The arguments have been noted but have not been persuasive because Rule 1.146 clearly states that "In the first action on an application containing a generic claim and claims restricted separately to each of more than one species embraced thereby, the examiner may require the applicant in his response to that action to elect that species of his or her invention to which his or her claim shall be restricted if no generic claim is held allowable". Further, upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Oath/Declaration

Art Unit: 1642

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because:

The address of Inventor Krone is crossed out but not initialed and no date of amendment has been disclosed.

Specification

4. The specification on page 1 should be amended to reflect the abandoned status of the parent application serial number 08/449,903.

Claim Rejections - 35 USC § 112

5. Claims 31, 33, 40 and 41 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31, 33, 40 and 41 are indefinite because claim 31 recites the phrase “disposed in a specimen”. The claim is confusing because it is not clear how the analyte is disposed in the specimen, for example, is it added to the specimen, is it naturally occurring, is it conjugated to another moiety, is the analyte processed in some way? The instant rejection can be obviated by amending the claim to delete the term “disposed”.

Claims 31, 33, 40 and 41 are indefinite because claim 31 recites the phrase “ensuring that said specimen contains an internal reference species”. The claim is confusing because the language is convoluted and difficult to understand. The instant rejection can be obviated by amending the claim to read “a) combining said

Art Unit: 1642

specimen with an internal reference species (IRS) of known concentration in order to calibrate all subsequent steps; whereby said combination is referred to as an IRS-containing specimen”.

Claim Rejections - 35 USC § 102

6 The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 31, 33, 40 and 41 are rejected under 35 U.S.C. § 102(b) as being anticipated by van Ginkel et al (J. Of AOAC International, 1992, 75:554-560).

The claims are drawn to a method for quantifying an analyte in a specimen comprising combining an internal reference species (IRS) in a known concentration to calibrate all subsequent steps with the analyte in the specimen, capturing and isolating said analyte and IRS by combining them with an affinity reagent, quantifying said analyte using mass spectrometric analysis to resolve distinct signals for said analyte and said IRS to determine the ratio of the analyte signal to the IRS signal wherein said quantifying step further comprises using working curve analysis which comprises first obtaining a mass spectrum of a first portion of said IRS containing specimen then making a plurality of standard preparations each containing a known but differing amount of said analyte and each containing a known or equal amount of said IRS, then obtaining respective mass spectra of each

Art Unit: 1642

whereby said respective mass spectra provide a working curve relationship of mass spectra relative to analyte concentration and then using said first mass spectrum and the standard preparation mass spectra working curve relationship to quantify said analyte.

Van Ginkel et al teach a method for quantifying an analyte in a specimen comprising combining an IRS, an isotopically labeled internal standard for quantification and quality control (p. 555, col 1), in a known concentration to calibrate all subsequent steps with the analyte in the specimen (p. P. 556, col 1), capturing and isolating said analyte and IRS by combining them with an affinity reagent (p. 556, col 2), wherein the processed specimen is analyzed by mass spectrometric analysis which resolves distinct signals for the analyte and for the IRS (p. 556, col 2) wherein the quantification of the analyte is determined by the ratio of the analyte to the internal standard (that is the first mass spectrum of a first portion of the IRS containing specimen) and the quantification procedure used includes a linear calibration curve which is fitted with the ratio of abundance of the ions in question (i.e. tert-butyl-beta-agonists/internal standards) as the independent variable and the concentration of standard (ng/injection vial) as the dependent variable which procedure yields linear calibration curves with an intercept not significantly different than zero (pl 556, col 2) which inherently requires a plurality of standard preparations each containing a known but differing amount of said analyte and each containing a known or equal amount of said IRS to produce said linear calibration curve.

8. No claims allowed.

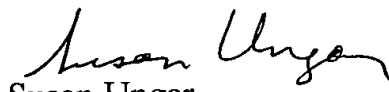
Art Unit: 1642

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar

September 16, 1999